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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/876,304	06/07/2001	Isiah M. Warner	9802.2 Warner	1549

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PATENT DEPARTMENT
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EXAMINER

AUDET, MAURY A

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 12/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/876,304	Applicant(s) WARNER ET AL.	
	Examiner Maury Audet	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-23 and 45-53 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18-23 and 45-53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
 a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicant's amendment and affidavit filed 9/25/03 is acknowledged. Claims 18-23 and 45-53 are pending.

35 U.S.C. § 112, 1st ¶, Written Description

The rejection of claims 18-21 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the *claimed invention*, is maintained for the reasons of record. Applicant's arguments filed 9/26/03 have been fully considered but they are not persuasive.

Again, *the claimed invention*, specific to claims 18-21, is drawn to:

“a polymerized dipeptide chiral micelle; wherein the micelle is *not* a polymer of a compound selected from the group consisting of N-undec-10'-enoyl-L-prolyl-L-glutamic acid, N-undec-10'-enoyl-L-methionyl-L-glutamic acid, and n-undec-10'-enoyl-L-phenylalanyl-β-alanine (cl. 18); or wherein the micelle comprises a polymer of monomers, wherein each of said monomers comprises an unsaturated hydrocarbon chain linked to a chiral peptide (cl. 19); or wherein said micelle comprises a co-polymer of a plurality of different dipeptide chiral surfactant monomers (cl. 21).” The invention is also drawn to a “composition of matter comprising a mixture of a plurality of different polymerized chiral micelles, wherein each of said polymerized chiral micelles is a micelle as recited in claim 18” (cl. 20).

Applicant argues that the Office has not rebutted the “. . . presumption that an adequate written description of the **claimed invention** is present when the application is filed” (MPEP §2163, subpart (I)(A), 1st ¶ (citation omitted)(emphasis added). However, to facilitate prosecution, Applicant has given some *examples* of portions of the specification where support for the claims may be found. For clarity in addressing the arguments, these sections have been

copied below from the specification (scanned into the USPTO image-file wrapper). The examiner notes that these are examples only, and that these examples, along with other parts of the specification, will be addressed as part of the arguments:

I. Claim 18 -

A. Page 18, lines 20-21:

It has been discovered that polymerized dipeptide [or oligopeptide] chiral surfactants greatly enhance the chiral separation of many racemic mixtures.

B. Page 33, lines 9-19:

Dipeptide chiral micelle polymers in accordance with the present invention may be used as mobile phase additives for chiral separations in capillary electrophoresis, or in micellar liquid chromatography under reversed phase conditions. *Our method of preparing chiral micelle polymers is easy to implement, and readily lends itself to use with a variety of polymers having different structures and degrees of chirality, which can be manipulated to enhance the chiral separations for particular analytes.* Using synthetic means known in the art, the chiral centers can be moved to different locations along the individual monomers, and the number of chiral centers per micelle can be increased or decreased by using micelles with higher or lower aggregation numbers respectively. Different monomer lengths may readily be generated through means known in the art. Fatty acid-type monomers terminating in double bonds are preferred, because such monomers may be used in the synthetic scheme described above with minimal modifications to the synthesis (emphasis added).

C. Page 34, new ¶ between lines 14-15:

An example of the present invention is a polymerized dipeptide chiral micelle, wherein said polymerized dipeptide chiral micelle is not a polymer of a compound selected from the group consisting of N-undec-10'-enoyl-L-prolyl-L-glutamic acid, N-undec-10'-enoyl-L-methionyl-L-glutamic acid, and N-undec-10'-enoyl-L-phenylalanyl-β-alanine. Another example of the present invention is a polymerized dipeptide chiral micelle as just described, wherein said micelle comprises a polymer of monomers, wherein each of said monomers comprises an unsaturated hydrocarbon chain linked to a chiral dipeptide.

II. Claim 19 - Also new ¶ between lines 14-15 (same as above):

III. Claim 20 - Page 33, lines 20-24:

Different, or mixed polymerized chiral micelles could be used in a separation, which can result in enhanced separation where the different micelles have complementary separation properties. *For example, a poly (sodium N-undecylenyl valine valine) micelle could be placed in solution with a poly (sodium N-undecylenyl phenylalanine phenylalanine) to take advantage of the different properties of their different resolving properties* (emphasis added).

IV. Claim 21 - Page 33, lines 25-31:

Alternatively, different chiral surfactant monomers may be copolymerized. Copolymers frequently have properties differing from those of either corresponding homopolymer. *For example, a surfactant monomer incorporating two L-valines could be combined with one incorporating two L-phenylalanines to form a mixed micelle; or both amino acids could be incorporated into the dipeptide monomer.* A polymerized micelle formed from this system would have chiral recognition properties similar to those of poly (L-SUVV), *in addition to the π -interaction chiral recognition properties of phenylalanine* (emphasis added).

Based on the examples above, it appears the specification *does provide adequate support for the use of any amino acids as the monomers to make up the dipeptides* of the polymerized dipeptide chiral micelles and compositions containing the micelles. Claims 23, and 45-53 only note the use of valine and leucine, but specification page 33, lines 20-31, describe that different monomers (i.e. phenylalanine) may also be used.

However, one of skill in the art would not recognize from the disclosure that the Applicant was in possession of the micelles, namely what specific compound polymers (cl. 18-21) are contemplated to work in the invention. The specification and claims do not provide adequate support for polymerizing the polymerized dipeptide chiral micelles and compositions containing the micelles, by any means or any compound capable of polymerizing peptides. The specification and claims (claims 23, and 45-53) only describe that such amino acid monomers

may be formed into dipeptides, and the claimed polymerized dipeptide chiral micelles and compositions containing the micelles, using “sodium N-undecylenyl”. See also specification page 20, lines 1-12 describing that:

All surfactants in this study were synthesized according to the procedure of Wang, J.; Warner, I. M. Anal. Chem. 1994, 66, 3773-3776. Surfactant monomers were prepared by mixing the N-hydroxysuccinimide ester of undecylenic acid with the appropriate amino acid or dipeptide to form the corresponding N-undecylenyl chiral surfactant.

It is suggested that Applicant amend claim 18, to expressly incorporate after “A polymerized dipeptide chiral micelle;” the language “wherein the dipeptide is polymerized by sodium N-undecylenyl; . . .” or language commensurate therewith to adequately describe the formation and resulting dipeptide structure of the dipeptides of the micelles and compositions therewith.

One of skill in the art would not recognize from the disclosure that the Applicant was in possession of a polymerized dipeptide chiral micelle, polymerized by any compound other than “sodium N-undecylenyl”. The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed” (see *Vas-Cath* at page 1116).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maury Audet whose telephone number is 703-305-5039. The examiner can normally be reached from 7:00 AM – 5:30 PM, off Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached at 703-306-3220. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-1234 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

MA

December 10, 2003



CHRISTOPHER R. TATE
PRIMARY EXAMINER